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the Agency may determine that any ingredient designated as active by an applicant is an inert ingredient if it fails to meet those criteria.

(c) If an ingredient is designated as an active ingredient, it must be identified in the label ingredients statement. If an ingredient is designated as an inert ingredient, it must be included as part of the total inert ingredients in the label ingredients statement.

(d) Designation of a substance as a pesticidally inert ingredient does not relieve the applicant or registrant of other requirements of FIFRA with respect to labeling of inert ingredients or submission of data, or from the requirements of the Federal Food, Drug, and Cosmetic Act with respect to tolerances or other clearance of ingredients.

[53 FR 15989, May 4, 1988, as amended at 60 FR 32096, June 19, 1995]

Subpart H—Coloration and Discoloration of Pesticides

SOURCE: 53 FR 15990, May 4, 1988, unless otherwise noted.

§ 153.140 General.

Section 25(c)(5) of the Act authorizes the Administrator to prescribe regulations requiring coloration or discoloration of any pesticide if the Administrator determines that such requirements are feasible and necessary for the protection of health and the environment. This subpart describes those pesticide products which must be colored or discolored.

[60 FR 32096, June 19, 1995]

§ 153.155 Seed treatment products.

(a) Pesticide products intended for use in treating seeds must contain an EPA-approved dye to impart an unnatural color to the seed, unless appropriate tolerances or other clearances have been established under the Federal Food, Drug and Cosmetic Act for residues of the pesticide.

(b) The following products are exempt from the requirement of paragraph (a) of this section:

(1) Products intended and labeled for use solely by commercial seed treaters, provided that the label bears a statement requiring the user to add an EPA-

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approved dye with the pesticide during the seed treatment process.

(2) Products intended and labeled for use solely as at-planting or hopper box treatments.

(3) Products which are gaseous in form or are used as fumigants.

(c) EPA-approved dyes for seed treatment are listed in:

(1) Sections 180.910, 180.920, and 180.950 if an exemption from the requirement of a tolerance has been established.

(2) Section 180.2010 if EPA has determined that residues of the dye will be present, if at all, at levels that are below the threshold of regulation.

(3) Section 180.2020 if it has been determined that no tolerance or exemption from the requirement of a tolerance is needed as a result of a determination by EPA that the use is unlikely to result in residues in food/feed.

[53 FR 15990, May 4, 1988, as amended at 66 FR 66772, Dec. 27, 2001; 69 FR 23117, Apr. 28, 2004]

Subparts I–M [Reserved]

PART 154—SPECIAL REVIEW PROCEDURES

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AUTHORITY: 15 U.S.C. 136a, d, and w.

SOURCE: 50 FR 49015, Nov. 27, 1985, unless otherwise noted.

Subpart A—General Provisions

§ 154.1 Purpose and scope.

(a) *Purpose.* The purpose of the Special Review process is to help the Agency determine whether to initiate procedures to cancel, deny, or reclassify registration of a pesticide product because uses of that product may cause unreasonable adverse effects on the environment, in accordance with sections 3(c)(6) and 6 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The process is intended to ensure that the Agency assesses risks that may be posed by pesticides, and the benefits of use of those pesticides, in an open and responsive manner. The issuance of a Notice of Special Review means that the Agency has determined that one or more uses of a pesticide may pose significant risks and that, following completion of the Special Review process, the Agency expects to initiate formal proceedings seeking to cancel, deny, reclassify, or require modifications to the registration of the product(s) in question unless it has been shown during the Special Review that the Agency's initial determination was erroneous, that the risks can be reduced to acceptable levels without the need for formal proceedings, or that the benefits of the pesticide's use outweigh the risks. Following completion of the Special Review process, a pesticide in question may be returned to the registration process.

(b) *Scope.* This part sets forth the substantive standards for initiating a Special Review of a pesticide product and the procedures for initiating and conducting the Special Review.

§ 154.3 Definitions.

(a) Except as otherwise defined in this section, terms defined in section 2 of FIFRA shall have the same definitions for purposes of this part.

(b) The term *Act* or *FIFRA* means the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, 7 U.S.C. 136 *et seq.*

(c) The term *Administrator* means the Administrator of the Environmental

Protection Agency or any officer or employee thereof to whom authority has been delegated to act for the Administrator.

(d) The term *confidential business information* means trade secrets or confidential commercial or financial information under FIFRA section 10(b) or 5 U.S.C. 552(b) (3) or (4).

(e) The term *other significant evidence* means factually significant information that relates to the uses of the pesticide and their adverse risk to man or to the environment but does not include evidence based only on misuse of the pesticide unless such misuse is widespread and commonly recognized practice.

(f) The term *person* means an applicant, registrant, manufacturer, pesticide user, environmental group, labor union, or other individual or group of individuals interested in pesticide regulation.

(g) The term *pesticide use* means a use of a pesticide (described in terms of the application site and other applicable identifying factors) that is included in the labeling of a pesticide product which is registered, or for which an application for registration is pending, and the terms and conditions (or proposed terms and conditions) of registration for the use.

(h) *Terms and conditions of registration* means the terms and conditions governing lawful sale, distribution, and use approved in conjunction with registration, including labeling, use classification, composition, and packaging.

(i) The term *validated test* means a test determined by the Agency to have been conducted and evaluated in a manner consistent with accepted scientific procedures

§ 154.5 Burden of persuasion in determinations under this part.

In making determinations under this part the Administrator shall be guided by the principle that the burden of persuasion that a pesticide product is entitled to registration or continued registration for any particular use or under any particular set of terms and conditions of registration is always on the proponent(s) of registration.